REMARKS

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

The rejection of claims 7-10, 14-16, 18-19, 26-27, 29-30, and 55-60 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,733,871 to Alps et. al., ("Alps") is respectfully traversed.

This is supported by the accompanying Declaration of Joseph A. Madri Under 37 C.F.R. § 1.132 ("Madri Declaration"). Dr. Madri has extensive expertise in the area of angiogenesis (Madri Declaration ¶ 3) and is, therefore, well suited to explain the deficiencies of Alps.

Alps relates to the treatment of neuronal damage in the central nervous system of individuals in need of such treatment (Madri Declaration ¶ 5). In particular, Alps relates to intravenous administration of pharmaceutically acceptable compositions of neurotrophic factors, such as bFGF, aFGF, NGF, CNTF, BDNF, NT3, NT4, IGF-I, and IGF-II, for treating or preventing neuronal damage as a consequence of ischemia, hypoxia, or neurodegeneration (Id.). Thus, Alps relates to administration of neurotrophic factors which target neurons to improve survival and limit damage (Id.).

Alps' method of treating neuronal damage would not have suggested to scientists in the field that the trk receptor ligands, brain derived neurotrophic factor ("BDNF"), NT-3, or NT-4, would be useful in inducing angiogenesis, as set forth in the present invention (Id. at ¶ 4). Nowhere does Alps disclose inducing angiogenesis in a patient that has cardiac ischemia or a vascular disorder by administering BDNF, NT-3, or NT-4 (Madri Declaration ¶ 6). In its examples, Alps uses focal or global ischemia models to induce neuronal damage (Id.). However, such models are used to create the symptom that Alps is interested in treating—i.e. neuronal damage (Id.). There is no indication in Alps that the underlying condition causing neuronal damage in Alps is being treated or is capable of being treated in accordance with the present application (Id.). There is also no indication that Alps is inducing angiogenesis with BDNF, NT-3, or NT-4 as in the present invention (Id.). All Alps is doing with these neurotrophic factors is what was well known in the art to use them for—treating neuronal conditions (Id.).

The present invention goes beyond the known use of such factors and involves the discovery that BDNF, NT-3, and NT-4 can be used for the very different purpose of inducing angiogenesis (Madri Declaration ¶ 7).

The factors that Alps identifies as neurotrophic factors are wide ranging and, while they include BDNF, NT-3, and NT-4, they go well beyond them (Madri Declaration ¶ 8). Indeed, the bulk of the experimental work set forth in Alps is with bFGF which, unlike BDNF, NT-3, and NT-4, is not a trk receptor ligand (Id.). In the sentence bridging columns 4 and 5 of Alps, it is stated that "[s]ome neurotrophic factors are also capable of promoting neurite outgrowth and glial cell and blood vessel restoration or inducing cells to secrete other neurotrophic factors (emphasis added)" (Id.). However, in column 9, lines 39-49 of Alps, it is made clear that, with regard to promoting blood vessel formation, Alps is only talking about bFGF. Alps's acknowledgement that bFGF achieves angiogenesis is no surprise, because the ability of bFGF to do so was well known in 1999 (Id.).

What was not known even when the present application was filed in 1999 was that BDNF, NT-3, or NT-4 have the ability to promote blood vessel formation (Madri Declaration ¶ 9). These molecules, at that time, were regarded as neurotrophic factors having no relevance to inducing angiogenesis (Id.). Thus, the indication in Alps (column 9, lines 42-45) that the non-trk receptor ligand, bFGF, is a potent "'gliotrophic' factor that promotes the proliferation of brain glial cells (including astroglia and oligodendroglia), as well as an 'angiogenic' factor that promotes the proliferation of brain capillary endothelial cells and blood vessels" was limited to bFGF (Id.). This statement would not have suggested to those in the field that BDNF, NT-3, or NT-4 are useful in promoting angiogenesis (Id.).

Thus, scientists skilled in the area of angiogenesis, reading Alps would not have not have regarded Alps as teaching that BDNF, NT-3, or NT-4 would be useful in inducing angiogenesis (Madri Declaration ¶ 10).

Since Alps clearly does not teach the claimed invention, it cannot be anticipatory and, therefore, the rejection based on this reference should be withdrawn.

The rejection of claims 7, 9-10, 14-16, 18-19, and 55-60 under 35 U.S.C. § 112(1st para.) for lack of enablement is respectfully traversed in view of the above amendments.

In view of all the foregoing, it is submitted that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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